

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q63803

Hisao HIRAMATSU, et al.

Appln. No.: 09/817,251

Group Art Unit: 1723

Confirmation No.: 8044

Examiner: Tony G. Soohoo

Filed: March 27, 2001

For: METHOD FOR STIRRING LIQUID

DECLARATION UNDER 37 C.F.R. § 1.132

Commissioner for Patents
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Sir:

I, Hironobu Oota, do declare and state that:

I graduated from Doshisha University, Faculty of Engineering, Department of Applied Chemistry in March, 1993.

Since April 1993, I have been employed by Kyoto Daiichi Kagaku Co., Ltd. (present name: ARKRAY, Inc.), and since that time, have engaged in development of small-sized biochemical analysis apparatuses and reagents therefore, development of small-sized immunological analysis apparatuses and reagents therefore, and study of mechanism systems and arithmetic processing systems such as stirring mechanisms, types of optical measurement, arithmetic processing method and magnetic card specification.

I am familiar with the prosecution of the above-identified patent application including the Office Action dated August 7, 2007.

The following experiment was conducted by me or my direct supervision in order to demonstrate the superiority of the method of the present invention in comparison with references JP 62-184357 and U.S. Patent 5,555,767, taken individually or in combination with one another.

<Methods and Conditions for the Experiment>

The experiment disclosed in the Declaration under 37 C.F.R. § 1.132 filed December 24, 2003 was conducted again, using multiple hematocrit values. The following experiments 1) to 4) were carried out for the cases where hematocrit values (Hct values) of whole blood were 20, 40 and 60%.

- 1) The total blood (100 μ L) was allowed to stand for not shorter than 1 hour in a sealed container used for the present invention so that it was completely precipitated.
- 2) The completely precipitated whole blood was stirred by using a nozzle according to the following conditions A to F. The top of the nozzle was inserted into the blood until the center of the depth and the following stirred amount was sucked and then discharged. The stirring was carried out 9 times.

As to a Reference, the blood which was completely stirred using a touch mixer under the following condition was used. (The reference was prepared for each hematocrit value of the total blood.)

Table 1: Experimental Conditions (A and D correspond to the present invention.)

Condition	Specimen Amount	Stirred Amount	Discharging Position(s)		Remarks
A	100 μ L	70 μ L	In the air	Right and left	The present invention
B	100 μ L	70 μ L	In the air	Center	Comparison (JP '357)
C	100 μ L	70 μ L	In the liquid	Center	Comparison (US 5,555,767)
D	100 μ L	30 μ L	In the air	Right and left	The present invention
E	100 μ L	30 μ L	In the air	Center	Comparison (JP '357)
F	100 μ L	30 μ L	In the liquid	Center	Comparison (US 5,555,767)
Reference	Total blood which was completely stirred with a touch mixer was used				

3) After stirring, 10 μ L of the total blood in the area to the depth of one half of the container was taken out and mixed, using a touch mixer, with 1 mL of hemolyzed liquid which was placed in a dispo-microtube being prepared separately.

4) Absorbance of the hemolyzed liquid was measured using an apparatus (SP-IM; manufactured by ARKRAY, INC.; wavelength: 568 nm) which was exclusive for such a purpose. It was conducted under each condition where n 5 and mean value, standard deviation and coefficient of variance (C. V.) were also calculated.

<Result of Experiments>

The results of the experiments are shown in the graphs 1-1 through 3-2 seen on the attached sheet.

I hereby declare further that all statements made herein are of my own knowledge and are true and that all statements made on information and belief are believed to be true; and further

that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: January 28, 2008

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